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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,117	02/02/2001	Stephen L. Dewey	BSA 00-34	9414

26302 7590 07/29/2003

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/776,117	Applicant(s) DEWEY ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) *32-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31 and 47-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application is a continuation in part of 09/209952 which is a continuation in part of 09/189166 which is a continuation in part of 09/129253.

Election/Restrictions

Applicant's election without traverse of the invention of Group I, Claims 1-16, 17-31, and 47-96 drawn to methods for diminishing, inhibiting, or eliminating addiction of drugs or abuse in a mammal in Paper No. 7, submitted May 6, 2003 is acknowledged.

Claims 34-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-16, 17-31, and 47-96 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular compound employed in a composition disclosed in claim 5 for example and in the specification, does not

reasonably provide enablement for the employment any compounds employed in any compositions that increase central nervous system GABA levels in a mammal for the claimed methods of the particular treatments herein, i.e., diminishing, inhibiting, or eliminating addiction-related behavior of a mammal.

These recitations, "a composition that increase central nervous system GABA levels in a mammal", is seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to methods of diminishing, inhibiting, or eliminating addiction-related behavior of a mammal.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on any compositions that increase central nervous system GABA levels in a mammal for the claimed methods of treatment herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants in the claims herein, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997). The CAFC clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphasis added).

In the instant case, "a composition that increase central nervous system GABA levels in a mammal", recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides those particular compounds having the functional property recited herein for the claimed method of treatment herein (see claim 5 for example).

Thus, the instant specification fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph, since it fails to provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of

monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, except those particular compounds of formula disclosed in the specification, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the claimed method of treatment herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects for methods of diminishing, inhibiting, or eliminating addiction-related behavior of a mammal, side effects, and especially serious toxicity that may be generated when and/or after administering any compounds encompassed by the claims to a host. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed, 1996) page 51 in

particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added).

In the instant case, in the absence of fully recognizing the identity of the members genus herein except those particular compounds of formula in the specification, one of skill in the art would not be able to fully predict the possible treatments herein and possible adverse effects occurring with many compounds having claimed functional properties to be administered to a host in the claimed method herein. Thus, the teachings of the "Goodman & Gilman's" book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

It is noted that only one particular compound, topiramate, employed in a composition for the treatments herein, was tested in the working examples herein (see page 43-91). Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active agents in the claimed composition. See MPEP § 716.02(d).

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having the function recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations to be administered to a host employed in the claimed methods of the particular treatments herein, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62-76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for the **preventing** addition to drugs in a mammal. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to a method for the **preventing** addition to drugs in a mammal.

The state of the prior art: The skilled artisan would view that the treatment to prevent addition to drugs in a mammal totally, absolutely, or permanently, is highly unlikely.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that the treatment to prevent addition to drugs in a mammal totally, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to prevent addition to drugs in a mammal.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations to be administered to a host employed in the claimed methods of the particular treatments herein, with no assurance of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,057,368.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method for changing addiction-related behavior of a primate comprising administering a composition including gamma vinyl GABA.

The claims of the instant application is drawn to methods of diminishing, inhibiting, or eliminating addiction-related behavior of a mammal including a primate comprising administering a composition that that increase central nervous system GABA levels in a mammal, which encompassing a composition comprising gamma vinyl GABA.

One having ordinary skill in the art would clearly recognize that the method in the patent and the method in the instant application are seen to substantially overlap since the methods in the instant application encompassing the method in the patent.

Thus, the instant claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,057,368.

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,541,520.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method for changing addiction-related behavior of a primate comprising administering a composition including gamma vinyl GABA.

The claims of the instant application is drawn to methods of diminishing, inhibiting, or eliminating addiction-related behavior of a mammal including a primate comprising administering a composition that that increase central nervous system GABA levels in a mammal, which encompassing a composition comprising gamma vinyl GABA.

One having ordinary skill in the art would clearly recognize that the method in the patent and the method in the instant application are seen to substantially overlap since the methods in the instant application encompassing the method in the patent.

Thus, the instant claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,541,520.

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,323,239.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method for changing addiction-related behavior of a primate suffering from addition to alcohol comprising administering a composition including gamma vinyl GABA.

The claims of the instant application is drawn to methods of diminishing, inhibiting, or eliminating addiction-related behavior of a mammal (including a primate) suffering from addition to substances broadly herein including alcohol, comprising administering a composition that that increase central nervous system GABA levels in a mammal, which encompassing a composition comprising gamma vinyl GABA.

One having ordinary skill in the art would clearly recognize that the method in the patent and the method in the instant application are seen to substantially overlap because of the methods in the instant application encompassing the method in the patent.

Thus, the instant claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65, and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,323,239.

Claims 1-7, 9-16, 17-22, 24-31, 47-52, 54-67, and 69-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,395,783.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to methods for changing addiction-related

behavior of a mammal suffering from addition to phencyclidine (PCP) and/or ameliorating effects pf PCP addition comprising administering a composition including gamma vinyl GABA, or administering the effective amount of gabapertin (see particularly claims 14-15 and 24-25), or administering the effective amount of progabide (see particularly claims 18-19 and 28-29), or administering the effective amount of fengabine (see particularly claims 20-21 and 30-31), or administering the effective amount of GABA (see particularly claims 22-23 and 32-33), or administering the effective amount of topiramate (see particularly claims 16-17 and 26-27).

The claims of the instant application is drawn to methods of diminishing, inhibiting, or eliminating addiction-related behavior of a mammal suffering from addition to substances broadly herein including PCP, comprising administering a composition that that increase central nervous system GABA levels in a mammal, which encompassing a composition comprising gamma vinyl GABA, or administering effective amount of gabapertin, progabid, fengabine, GABA, or topiramate.

One having ordinary skill in the art would clearly recognize that the method in the patent and the method in the instant application are seen to substantially overlap since the methods in the instant application encompassing the method in the patent.

Moreover, the method steps of the instant application are same as the method steps in the patent.

Thus, the instant claims 1-7, 9-16, 17-22, 24-31, 47-52, 54-67, and 69-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,395,783.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 17-31, and 47-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (5,189,064 PTO-892) and Phillips (3,639,607, PTO-1449 submitted April 13, 2001) in view of Costa et al. (5,302,583, PTO-892) and Minchin et al. (5,538,956, PTO-892) and Carmosin et al. (5,332,736, PTO-892).

Blum et al. discloses that GABA and GABA agonists are useful broadly in methods for the treatment of addiction or abuse of drug such as cocaine and alcohol (see 5,189,064 abstract, col.4 lines 30-32 and 64 and 66 in particular) since GABA and GABA agonists increase GABA levels in a mammal (see col.5 lines 2-5).

Phillips discloses that anticonvulsants are known to be useful broadly in methods of treatment of tobacco addiction, i.e., smoking, and also treating anxiety which accompanies the withdrawal or reduction of the smoking habits in a mammal. See col.1-2.

Blum et al. and Phillips do not expressly disclose the employment of the particular GABA and GABA agonists or anticonvulsants herein and their effective amounts in methods of treating addition-related behavior of a mammal or drug additions herein in a mammal.

Costa et al. discloses that valproic acid and gabapentin are known anticonvulsants which are known GABA agonists (see col.4 lines 56-60).

Minchin et al. discloses that fengabine and progabide are known GABA agonists (see col.1 lines 55-56, col.2 lines 13-15).

Carmosin et al. discloses that topiramate is an anticonvulsant which is known GABA agonists (see col.2 lines 24-25), and gabapentin and progabide are known GABAs (col.1 line 60 to col.2 line 23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular GABA and GABA agonists or anticonvulsants such as valproic acid and gabapentin, GABA, fengabine, progabide and topiramate and their effective amounts in methods of treating addition-related behavior of a mammal or drug additions herein in a mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular GABA and GABA agonists or anticonvulsants such as valproic acid and gabapentin, GABA, fengabine, progabide and topiramate in methods of treating addition-related behavior of a mammal or drug additions herein in a mammal, since anticonvulsants, GABA, or GABA agonists are known to be useful in methods of treating addition-related behavior of a mammal or drug additions herein broadly according to the prior art. Valproic acid and gabapentin, GABA, fengabine, progabide and topiramate are all known anticonvulsants, GABA, or GABA agonists.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular anticonvulsants, GABA, or GABA agonists such as valproic acid and gabapentin, GABA, fengabine, progabide and topiramate would have same therapeutic usefulness in methods of treating addition-related behavior of a mammal or drug additions herein in a mammal. Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of these known anticonvulsants, GABA, or GABA agonists used in the methods herein because the optimization of known effective amounts of known active agents to be administered is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
July 22, 2003